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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,042	02/19/2002	Donald C. Roe	8430	4980

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EXAMINER
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KOPPIKAR, VIVEK D

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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09/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/078,042

Applicant(s)

ROE ET AL.

Examiner

Vivek D. Koppikar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the Application*

1. Claims 1-10 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on August 8, 2007.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 5-7 and 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6, 319, 199 to Sheehan in view of US Patent Number 6,055,506 to Frasca, Jr.

A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Col. 4, Ln. 54-67).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least one analysis selected from the

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group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca, Jr.: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(B) As per claim 2, in the system of Sheehan in view of Frasca, Jr. the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

(C) As per claim 5, in the system of Sheehan in view of Frasca, Jr. the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 6, Sheehan in view of Frasca, Jr. teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);

d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67);

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

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c) at least one data analysis mechanism generating information pertaining to the health of an individual (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(E) As per claim 7, in the system of Sheehan in view of Frasca, Jr. at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32).

(F) As per claim 9, Sheehan in view of Frasca, Jr. teach a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

a) selecting at least one health parameter appropriate for the particular individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);

b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);

c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46); and

e) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

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d) analyzing the data via at least one data analysis mechanism to define at least one of an out-of-control situation requiring intervention and/or potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

(G) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca and in further view of US Patent Number 5,464, 102 to Falcone and in even further view of US Patent Number 6,540,674 to Zadrozny.

(A) As per claim 8, the system of Sheehan in view of Frasca, Jr. includes:

- a) a data measurement mechanism generating data relevant to a particular health condition of the individual (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

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d) an information presentation mechanism displaying to the individual the information pertaining to the health of an individual, wherein the at least one information presentation mechanism is selected from the group: a graphical summary screen, an icon based summary screen, a help guide, an anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Frasca: Col. 13, Ln. 58-Col. 14, Ln. 6). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not teach that the data acquisition mechanism is adapted to perform a preliminary analysis on the data and provide an output (e.g. an alarm) when the data comprises a value that is outside of a control limit, however, this feature is taught by Falcone (Col. 2, Ln. 9-18 and Col. 4, Ln. 22-25). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca with the aforementioned teachings from Falcone with the motivation of having a detection means whenever a patient's state was altered, as recited in Falcone (Col. 1, Ln. 5-10).

Sheehan in view of Frasca, Jr. in view of Falcone do not teach that the information includes at least one level of intervention (i.e. recommendation) when the data comprises a value

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that is outside of a control limit, however, this feature is taught by Zadrozny (Col. 2, Ln. 33-38 and Col. 10, Ln. 28-32). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Falcone with the aforementioned teachings from Zadrozny with the motivation of having a means of recognizing events which pose a danger to ill persons and providing assistance to these ill persons, as recited in Zadrozny (Col. 2, Ln. 4-9).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr., as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Ekblad with the motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.



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6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr., as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.

(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

#### *Response to Arguments*

7. Applicant's arguments filed on August 8, 2007 have been fully considered but they are not persuasive. The applicant's arguments will be addressed in the same order as they were addressed in the "Remarks" filed on August 8, 2007.

(1) Applicants have amended claim 8 and have argued that the prior art references used in the last Office Action dated May 21, 2007 do not teach these amended features. This argument is now moot in view of the new grounds of rejection of claim 8, set forth above.

(2) Applicants argue that neither Sheehan nor Frasca, Jr. teach a population comparison. However, the Office would like to point out that the Frasca, Jr. reference does in fact teach a population comparison (Col. 3, Ln. 21-26) since a patient's data is compared with a predetermined limit. This predetermined limit in Frasca, Jr. must inherently be derived from a population of more than one individual based on past experience that the hospital (or other hospitals) have had with treating other patients for the same clinical condition as the outpatient is

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being treated for because Frasca, Jr. does not state that the predetermined limit is generated based the outpatient's own data.

(3) With regard to Claim 7, applicants argue that the Sheehan reference does not teach or suggest that the data acquisition mechanism includes a PDA. However, Sheehan states that a base unit in Sheehan can communicate with a wide range of external devices including wireless transceivers. The Office takes the position that a PDA or handheld PC is a form of a wireless transceiver.

### ***Conclusion***

8. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

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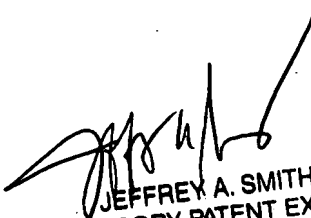
If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

  
Vivek Koppikar

8/31/2007

  
JEFFREY A. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600